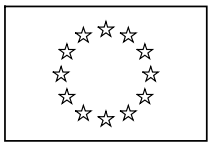

EUROPEAN COMMISSION

EU Priority Proposals

for Regulatory Reform in Japan

16 October 2003

Table of Contents

Introduction

The European Union once again thanks the Government of Japan for the opportunity to make a contribution, through the EU-Japan Regulatory Reform Dialogue, to Japan's rolling programme of regulatory reform. The EU hopes that its input will serve as a point of reference for the recommendations of the Council for Regulatory Reform (CCR) expected at the end of this year, and that the Government of Japan will be able to take up as many as possible of the EU's proposals.

Developments over the past years in the Japanese economy make systematic economic restructuring and regulatory reform measures all the more necessary. The constraints on stimulating demand through fiscal and/or monetary and exchange rate policies are more clearly understood. Thus, the need to address structural and regulatory obstacles which at present inhibit business activity, entrepreneurial initiative and the competitiveness of the Japanese economy has become all the more apparent. Moreover, measures to improve conditions in segments of the economy like the financing of SMEs, development of the information society, efficient health care, etc. cannot be implemented successfully without tackling structural problems in the economy more broadly. This applies in particular, to the need to revitalise the business environment in a comprehensive and systematic way.

The EU, like Japan, considers the bilateral dialogue on regulatory reform to be a valuable channel to discuss problem issues which affect not only EU, but also Japanese companies doing business in the Japanese market and to identify and advance solutions to these problems. The joint Action Plan, a set of medium-term co-operation initiatives adopted at the December 2001 EU-Japan Summit in Brussels, and intended to strengthen political and economic links, renews both sides' commitment to making the regulatory reform dialogue more efficient and effective. The EU and Japan have already taken steps to streamline the exercise and to pinpoint priorities more clearly. At the bilateral summit of May 2003, Prime Minister Koizumi called again for more EU firms to invest in Japan, as well as for continuing structural reform efforts at home. This underpins our common ambition to make the regulatory reform process in Japan and our bilateral dialogue even more fruitful.

The EU welcomes the positive developments over recent years in a number of areas. Considerable efforts are now being undertaken to attract more foreign direct investment (FDI) into Japan. In the insurance sector, the regulatory framework has improved considerably. Market access in the asset management business has substantially widened. Approval times for pharmaceutical drugs have been reduced considerably. Protection of IPR and labour rules have also seen some positive developments. Three areas deserve special mention: legal services, competition policy and the investment environment.

Concerning legal services, the Diet passed legislation in July 2003 which will remove the prohibition against Japanese lawyers (*bengoshi*) and foreign lawyers admitted to practice in Japan (*gaiben*) forming partnerships and *bengoshi* from being employed by foreign law firms in Japan. Once implemented, it is expected that this

legislation will largely meet the EU's regulatory reform requests to Japan in the area of legal services. The EU welcomes the new legislation and commends the Government of Japan for these changes, which will foster the further development in Japan of law firms offering integrated international legal services and will substantially improve the business environment to the benefit of both domestic and foreign companies.

In the area of competition policy, there have also been significant and positive developments as of late, corresponding to requests made by the EU in previous years. Effectively from 9 April 2003, the Japanese Fair Trade Commission (JFTC) was transferred back under the authority of the Cabinet Office, thus securing its independence from the MPHPT which still retains responsibilities for the promotion of certain sectors of the economy, such as post and telecommunication.

Following the signature of the Agreement concerning co-operation on anti-competitive activities on 10 July 2003, the EU looks forward to an enhanced exchange of information and co-operation with Japan, to the benefit of consumers both in Japan and Europe. The EU continues fully to support the JFTC's objective strictly to enforce competition rules, and welcomes its increasing efforts to clamp down on bid-rigging and to tackle anti-competitive behaviour in the public utility sector. Vigorous and pro-active pursuit of competition policy is at the heart of a healthy, open, balanced and modern economy. It not only vital in order to create conditions which ensure that investment decisions are made on a rational and efficient basis, but also for improving the domestic and international competitiveness of Japanese companies, removing barriers for new entrants to the markets and bringing down basic input costs. Weak competition policy, on the other hand, gives incumbent suppliers the upper hand over new entrants and all too often snuffs out the sparks of innovation.

The announcement, made in June 2003, to review the Anti-monopoly Act (AMA) in order to adjust the law to the rapidly changing market environment, focusing particularly on the regulations in the public utility sector such as telecommunications, energy and airlines, and the issue of parallel price increases in oligopoly markets, is very significant. It will be the first revision of the AMA since 1977. In this context, it will be of paramount importance to review the entire system of enforcement measures under the AMA, including elimination orders, surcharges and criminal charges.

The maximum amount for fines on legal persons was raised fivefold as of 29 June 2002, up to 500 million Yen, and a more fundamental revision of the surcharge system is now being considered, possibly in view of establishing a more discretionary system of administrative fines, as in the EU. This should help to pave the way for the introduction of an effective leniency policy in order to facilitate the detection and break-up of illegal cartel arrangements. The JFTC increased its staff again by 40 persons in FY 2003, mainly in the Investigation Bureau. The EU hopes that these recent staff increases will be continued so as to enable the JFTC effectively to fulfil its law-enforcement role and to reverse the two negative trends in its recent statistics, i.e. its case-handling efficiency and the backlog of cases. It is also hoped that the investigative powers of JFTC officials will be further increased.

If these changes were to translate into a more systematic and bold enforcement of antitrust violations over the coming years, this would have an invigorating effect on the competitive landscape of the Japanese economy and would satisfy the major requests the EU has tabled under the Regulatory Reform Dialogue with Japan.

As far as the investment environment is concerned, the EU welcomes the significantly more pro-active attitude being taken by the Government of Japan towards the promotion of FDI. In his policy speech to the Diet on 31 January 2003, Prime Minister Koizumi announced the intention to make Japan an attractive destination for foreign firms and to double the cumulative stock of foreign direct investment in five years. His speech was followed by a report of the Japan Investment Council (JIC) on 27 March 2003 on further measures to increase FDI inflows. The JIC's Expert Committee then announced a program for promoting inward FDI in Japan, covering five areas and 74 policies. Other major milestones were the launch of the Invest-Japan scheme, the opening of the Invest-Japan Business Support Centre by JETRO on 26 May 2003, and FDI-promotion campaigns to attract more investors from the EU to Japan (events scheduled in Stockholm, Helsinki, Paris and Munich, in November and December 2003).

Increasing two-way investment is also one of the key aims of the EU-Japan Action Plan adopted at the EU-Japan Summit in December 2001. The Athens summit in May 2003 reaffirmed this policy orientation. Annexed to the Joint Press Statement issued at the summit, a document entitled "EU-Japan initiatives on Investment" called on both sides to realise the full potential of two-way investment flows. It mentions, in particular, the high level Regulatory Reform Dialogue as a means to address issues affecting the local investment and business environment. It also refers to the domestic initiatives which the Government of Japan is taking to implement the five-pillar programmes to promote investment to Japan which were decided by the Japan Investment Council, and to promote deregulation initiatives of various kinds, including through the Special Zones for Structural Reform.

The specific reference to deregulation in the context of FDI promotion is important. Indeed, the European Union would like to stress that many of the reform proposals mentioned in other chapters of this document are, if acted upon, designed to have a beneficial effect on the overall investment climate and may trigger new FDI flows into Japan, even though they may not seem to be FDI-specific at first sight. Direct investment in Japan is still very limited compared to the EU and the US. There has been a significant pick-up in the inflow since FY 1998, with a peak in FY 2000 and lower but stable figures for FY 2001 and FY 2002. FDI has made most headway in Japan in sectors where deregulation has progressed (like financial services and telecommunications), suggesting that if regulatory reform and economic restructuring can be advanced on a broader basis in Japan, inward foreign direct investment will follow. Special Zones for Structural Reform also offer the possibility of trialling regulatory reform measures on a local basis, although the EU believes that successful cases should be seen clearly in the perspective of pilot projects for future deregulation at national level.

The European Union commends the Government of Japan for the efforts undertaken so far. Major reform steps already undertaken over the last years include

- Starting in 1997, far-reaching changes in the Commercial Code which have allowed the creation of holding companies, streamlined merger procedures, allowed domestic share exchanges in order to facilitate corporate restructuring, improved bankruptcy rules, and strengthened corporate governance and accountability.

- Starting in 2000, a series of revisions in accounting standards in order to bring Japan nearer to international practice by introducing consolidated, tax effective and market-to-market accounting.

- Initial steps to improve labour mobility by introducing defined contribution portable pension plans (October 2001), gradually expanding the job categories covered by fee-charging employment agencies, and increasing the maximum duration of termed contracts.

- From 1999, moves to increase transparency and accountability in the regulatory process through the public comments procedure and the No-Action Letter system.

The five policy areas now to be tackled by the Government of Japan include (i) a review of administrative procedures aimed at making the process simpler and clearer through the establishment of a single contact point at each ministry, (ii) improvement of the business environment by facilitating cross-border mergers and acquisitions (M&A), (iii) improvement of employment and living conditions, (iv) improvement of local and national frameworks to assist local governments' autonomous efforts to attract FDI, and (v) dissemination of information within Japan and abroad.

On a less positive note, the EU would like to highlight the disappointing lack of progress over the past years on issues related to food safety and agricultural products.

1. Further improving the business environment

1.1 Further improving the business environment for Foreign Direct Investment (FDI)

Japan is increasingly developing policies to attract more foreign direct investment (FDI) into Japan. It is thus all the more important to support these efforts thorough the vigorous pursuit of structural and regulatory reforms. Unless Japan manages to rid itself from the myriad of constraints, regulations and procedures which have to be followed by investors, even the best FDI campaigns may only generate a limited return. Potential investors might consider, but not necessarily choose, Japan as a destination for FDI.

In this context, the EU welcomes and follows with interest the Special Zones for Structural Reforms. This new approach to deregulation has the advantage of opening opportunities for greater market access for EU business. It is important, however, to ensure transparent selection and non-discriminatory selection and establishment, and to apply successful examples on a nationwide basis. More generally, though many of the issues listed in this document may not seem to be investment-specific at first sight, many of them do have cross-sector implications and are intended, directly or indirectly, to improve the FDI environment in a broader sense. Moreover, the EU urges the introduction as soon as possible on a nationwide basis of initiatives which succeed in the special zones, in order to reap the full economic benefits and in the long run to avoid fragmentary regulatory frameworks.

Implementation remains of considerable concern to the EU. The improvements in the regulatory framework which the Japanese authorities are making or are planning will not work without a commitment by the government ministries or other bodies concerned to implement planned legal measures fully and energetically. Even for those sectors in which the EU has noted positive developments, such as the issue of legal services, the EU will closely monitor developments to assess whether policy changes decided by the government will effectively translate into business reality on the ground. In this context, we welcome the active and growing dialogue between the European Business Community in Japan and the relevant Japanese ministries.

1.1.1 Lowering the cost of doing business

Many of the basic recommendations made by Keidanren in 2002 ("Towards the Creation of International Investment Rules and Improvement of the Japanese Investment Environment", 16 July 2002) remain valid. Steps which the Japanese authorities should take to stimulate more direct investment include

- improving the efficiency and reducing the cost of energy, physical distribution, telecommunications, and social capital formation;
- lowering the effective corporate tax rate and reforming tax systems;
- creating more flexible corporate laws;
- simplifying and speeding up administrative procedures while eliminating arbitrary decisions;
- assisting creative efforts by local municipal governments such as special regulatory reform zones;
- simplifying, rationalizing and speeding up customs clearance procedures at ports

and customs;
- promoting the outsourcing of state-run programs to the private sector;
- developing capital markets and other institutions; and
- bringing Japan's technical regulations and standards and its conformity assessment procedures into line with international standards.

The EU continues to underline the high cost threshold for investors in Japan and the lack of transparency and predictability of the investment environment as two key areas for active reform. In addition, relaxing rules concerning human resources would also contribute to improving conditions for existing investors and attracting potential investors from overseas.

For a number of reasons there is, on international comparisons, a high cost threshold for a foreign investor entering the Japanese market. The European Union notes the positive effects which many of the newly established Special Zones for Structural Reforms may trigger for FDI. As an example, the Special Zones for International Physical Distribution with a 24 hours/365 days customs clearance operation are a very welcome step not only to facilitate trade operations, but, also to lower the entry thresholds for foreign investors. As a recent JETRO survey underlined, this measure is one of the most significant for the foreign business community, since it has a cross-sectoral impact and will increase Japan's overall openness for international business. The European Union encourages the Government of Japan to consider ways of applying this concept in a general fashion nationwide and to explore ways to further reduce handling fees.

The introduction of a consolidated taxation system in 2002 was most welcome and addressed a long-standing EU concern. However, a number of issues remain to be addressed if the system is to deliver its full potential in promoting investment and corporate restructuring. In the tax field in particular, a number of features of the current system have a significant cumulative negative impact on firms investing in Japan. These are the 2% surtax (unknown in the EU) levied on firms, the 100% ownership rule for application to subsidiaries, the expiry of companies' pre-consolidation losses, the obligatory taxable revaluation of assets on entry to a consolidated group, and the obligatory integration of all 100% subsidiaries to be eligible for consolidation. Moreover local taxes are not included in the consolidation.

Moreover, tax-neutral share-for-share exchanges, a common merger and acquisition (M&A) technique in other major markets, are not yet possible in Japan in a general manner. This is a matter of concern precisely because M&A is one of the main ways in which foreign companies can enter a market, and is a major channel for foreign investment. As of 9 April 2003, the Law on Special Measures for Industrial Revitalization allows cross-border "triangular" mergers (i.e. the use as consideration by a 100% Japanese subsidiary of its foreign parent company's shares when merging with/acquiring another Japanese company) if a Japanese company is in distress and if the company's revitalisation plan is approved by the Japanese Government. However, the Law fails to address taxation and thus the rules for qualified tax-neutral mergers are not applicable. When shareholders of that Japanese company purchase shares of a European company which is trying to acquire the Japanese company through its own Japanese subsidiary by way of "share-swap", they have to pay income tax under the existing Japanese tax laws even though they do not earn profits. While the recognition of triangular mergers by the Japanese legislation is thus welcome as such, the fact that it is so far tied to the revitalisation of a company and requires ministerial

approval means that the practical usefulness of this new instrument remains limited. Unfavourable tax treatment may well outweigh the incentive to conduct a triangular merger.

Criteria other than profits, such as capital and employee expenses, i.e. factor-based criteria, will become part of the (prefectural) Corporate Enterprise Tax effective April 2004. Such taxes discourage foreign direct investment and defy global trends by moving away from the principle of taxing in accordance with the ability to pay. The new Corporate Enterprise Tax will (in general) not allow foreign parent companies to obtain a full foreign tax credit on Japanese income.

In addition, companies in Japan have been operating in a challenging economic environment for much of the last decade. It would improve the Japanese business and investment environment by helping companies obtain full relief for all losses beyond the current five-year limit.

The tax authorities continue to make transfer pricing assessments based on secret comparisons about which the taxpayer has difficulties in confirming product or functional similarities. Moreover, the use of secret comparisons for audit assessments is inconsistent with the transfer pricing methodology of Advance Pricing Agreements, where company-level profitability of public companies is commonly used. This inconsistency in application of transfer pricing methodologies increases the difficulties faced by taxpayers.

The Japanese tax authorities focus heavily on the gross profit margins of individual products or groups of products. This focus penalises companies with ratios to sales of Selling, General & Administration costs (SG&A) that are lower than the ratios of comparable companies. These differences arise either from differences in intensity of function, or from differences in the actual functions and risks between the taxpayer and the comparable companies. Such differences should be recognised in making any transfer pricing adjustments.

The tax examiners continue to place too much weight on the belief that the Japanese market has special characteristics and barriers to entry, with the result that marketing intangibles of Japanese entities are given greater value than is actually deserved.

Priority reform proposals:

a. The EU urges the Government of Japan further to reinforce its strategic political approach to encouraging FDI by addressing as a priority the following issues:

(i) Continuing to improve the "mainstreaming" of pro-investment measures throughout government policy-making, for instance by taking a broad cross-sectoral approach to investment as a priority in itself under the Three-Year Regulatory Reform Programme, and in the work of the CRR.

(ii) *Assessing the impact which special zones for structural reforms have on the promotion of FDI and to enable nationwide application of those concepts. 24 hours/365 days customs clearance would be a prime example.*

b. *The EU urges the Government of Japan to facilitate* ***corporate reorganisation (including M&A activities)****:*

(i) *Allow for tax-neutral share-for-share M&A by foreign companies in all cases.*

(ii) *For tax assessment purposes at the time of a merger or acquisition, better clarify certain key concepts, such as "business" or "business continuity test".*

(iii) *Enable taxpayers to obtain formal advance clearance on whether or not an intended reorganisation complies with the conditions for qualified reorganisation.*

c. *The EU urges the Government of Japan to address industry's concerns and to enable companies to make effective use of the* ***consolidated tax system*** *and to*

(i) *Abolish the 2% surtax levied on companies electing to use the consolidated tax system. No such tax exists in Europe.*

(ii) *Reduce the ownership qualification for consolidation of subsidiaries from 100% to 50%.*

(iii) *Eliminate the expiry of pre-consolidation period losses of companies when they enter the consolidated group.*

(iv) *Eliminate the obligatory taxable revaluation of assets of companies entering the consolidated group.*

(v) *Eliminate the obligatory integration of all 100% subsidiaries if a group wishes a consolidation.*

(vi) *Include local taxes in the consolidation. The taxation system related to Corporate Inhabitant Tax (*hojin-jyumin-zei*) and the Corporate Enterprise Tax (*hojin-jigyo-zei*) should be simplified as much as possible in order to reduce the administrative burden in the preparation of related local tax returns.*

d. *The EU suggests eliminating* ***factor-based criteria*** *from the Corporate Enterprise Tax.*

e. *The EU suggests allowing for* ***carry forward of losses*** *beyond the current 5 year limit.*

f. *With regard to* ***transfer pricing****, The EU suggests to*

(i) *Base transfer pricing assessments only on information to which the taxpayer has access, and not on secret comparable information.*

(ii) *Ensure consistency between the transfer pricing methodology for audit assessments, and that used for Advance Pricing Agreements.*

(iii) *Allow for greater flexibility in the use of SG&A adjustments, in order to account for the effect of the SG&A expenses to sales ratio on gross margin levels.*

(iv) *To place less weight on special characteristics of the Japanese market.*

1.1.2 Transparency and predictability

An area of continuing concern is the transparency, accountability, predictability and independence of the regulatory process. Transparency means diffusion of information, i.e. making available relevant information for all interested operators in order to ensure fairness as well as economic efficiency, and is closely linked to the principle of legal security. A business survey conducted for the European Commission on global factors in deterring investment concluded in April 2000 that 71% of big EU companies regarded lack of transparency in legislation and regulations as the most frequent hindrance to investment. The problem is all the greater for SMEs. Unnecessary difficulties for companies making their way through the regulatory process result in a considerable penalty in time and money. There has been significant progress in this area in recent years, the two most notable developments being the introduction in April 1999 of the Public Comments Procedure, and in April 2001 of government-wide guidelines obliging each ministry to set up a "No Action Letter" system. However, the European Union remains concerned that, though welcome in intent, these procedures are often implemented in such a way as to prevent them from delivering their full potential. The following are amongst the EU's most important concerns:

- Regulators in many areas of economic activity in Japan lack independence**.** For example, Japan's telecommunications sector lacks an independent regulatory authority. In harbour transport, for instance, the Ministry of Land, Infrastructure and Transport (MLIT) delegates certain regulatory functions, including many with a bearing on free competition, to the Japan Harbour Transport Authority. This body represents all the major waterfront businesses except the shipping lines, but operates a "prior consultation" process for changes in shipping operations, which effectively binds the shipping lines. The EU echoes the concerns of the CRR, expressed in its July 2002 Interim Report, that a dedicated model of regulatory oversight is required for liberalising sectors dominated by state-owned monopolies, such as energy and postal services, and urges Japan to establish independent regulators in these sectors.

- Fundamental conflicts of interest such as the above contribute to a business environment which all too often unfairly favours incumbent operators over new entrants.

Steady progress is being made in Japan towards streamlining administrative procedures and practices, but the EU remains concerned by the continued prevalence of administrative guidance, both written and oral. In the process of regulatory reform, it is vital that regulations are not simply replaced by administrative guidance. The Public Comments Procedure, introduced in April 1999 to allow all interested parties to comment on administrative measures and draft regulations, is a vital part of this process. Significant improvements in the quality of consultation with regulatory authorities over recent years are reported by EU companies.

However, in order to achieve the intended aim of ensuring better regulation through timely prior consultation, the Public Comments Procedure needs to become an integral part of the regulatory process. While ministries and agencies are complying with the letter of the procedure, all too often only little time is left before finalisation

of the report or regulation in question for well-substantiated comments to be properly taken into account.

The "No Action Letter" (NAL) system has the capacity to save companies time and money by giving advance guidance on planned business situations. However, the number of NALs issued since the inception of the system is still very limited. In order to bring its intended benefits, the system needs to be implemented in a pro-active and consistent manner. In particular:

- Each administrative body has established its own "No Action Letter" (NAL) guidelines. This leaves open the risk of inconsistent application in terms of the criteria for the receiving of requests, including scope of application, and the degree to which a given ministry feels itself to be bound by its replies to requests. In addition, the system is restricted in application so-called "new business", rather than also permitting the clarification of regulatory issues involving existing products and services.

- Replies given by administrative bodies are not binding, thus giving rise to doubts about their reliability as the basis for major business decisions. It is obvious that every case needs to be treated on its own merits. However, there is a legitimate expectation by business that similar cases should receive similar treatment, and that previous cases may provide a yardstick to assess the feasibility of planned business transactions.

- There is no clear obligation to publish replies, thus depriving administrative bodies of a useful means of establishing, over time, a published body of reliable precedent.

- There is no clear appeals procedure in cases where a company feels that the reply it receives does not fit the facts of the case it has presented. The EU is concerned to have been informed of cases where officials have orally discouraged the submission of NALs.

Similar observations apply to the *kaito bunsho* system used by the National Tax Authority (NTA). A lack of clear and binding guidance regarding specific tax situations continues to be a persistent problem for European firms doing business in Japan. Firms report numerous cases of arbitrary and inconsistent treatment from tax authorities in Japan. It is still uncommon for clarifications on specific transactions to be issued in writing. With the exception of responses issued under the formal *kaito bunsho* system, no record of any specific guidance is made available to the public. This makes business planning difficult and inhibits firms from seeking effective redress when there is a dispute with a particular ruling.

The principles of transparency and accountability should apply not only to systems such as public comments and NALs established by law, but also to relations with the regulator in the course of day-to-day business. Although the EU recognises that increased transparency requires long-term changes in administrative culture, awareness-raising activities in government such a government-wide code of conduct and improved training would be constructive steps.

Priority reform proposals:

a. *With regard to the Public Comments procedure, the EU urges the Government of Japan to build on progress in implementation by:*

(i) *enforcing and monitoring its use by ministries and agencies, and in particular ensuring that a reasonable period (at least six weeks) is allowed for comments to be made; and*

(ii) *ensuring that ministries, agencies, and, where applicable, advisory councils, allow sufficient time properly to reflect considered public comments in draft regulations and reports. All public comments submitted should be published.*

b. *With regard to the "No Action Letter" (NAL) system (and, similarly, the NTA's* kaito bunsho *system), the EU urges the Government of Japan to:*

(i) *Monitor centrally the implementation of the system in order to ensure that consistent criteria for the receivability of requests, including scope of application, are applied. The scope of application of NALs should be increased to cover also regulatory issues involving existing and not just "new" products and services;*

(ii) *Make NALs binding on the issuing body;*

(iii) *Create a clear obligation on the issuing body to publish NALs, in anonymous form where necessary, in order to create over time a reliable body of precedent;*

(iv) *Establish clear guidelines allowing companies to appeal against a NAL if they feel that it does not properly reflect the facts of their case.*

c. *With regard to the NTA's administrative practice in particular, the EU urges the Government of Japan to ensure that all rulings and clarifications are provided in writing as a matter of standard practice, and not only for requests received under the formal* kaito bunsho *system. This should include requests for prior clearance for specific transactions.*

d. *Continue efforts to make competition rules more effective and improve* inter alia *enforcement of competition rules by extending statutory limitations and increasing the mount of fines that can be imposed.*

1.1.3. Human resources

Global economic pressures and changing circumstances in the Japanese business environment are forcing companies to re-evaluate their human resource management practices, with more focus on improving labour quality and management efficiency. The ability of companies to manage their human resources in an efficient and cost-effective manner will ultimately affect the health of the Japanese economy. One of the difficulties European firms continue to face doing business in Japan is securing internationally qualified Japanese employees for their Japanese operations.

The recent revisions to the Labour Standards Law do not clarify the situation surrounding dismissals in Japan to the desired extent. While the need for more flexibility was recognized by an advisory panel report submitted to the Ministry of

Health, Labour and Welfare (MHLW) on 26 December 2002, revisions to the Labour Standards Law that passed the Diet on 26 June 2003 only codified the right of companies to dismiss employees for justifiable reasons in line with accepted social customs, without further clarifying concepts such as "objectively justifiable reason" or "socially fair". While fixing the discrepancy between the Labour Standards Law (which until now has been silent on the subject of dismissals) and the Japanese Civil Code (which recognized the right of employers to dismiss employees), the changes do not set out specific criteria for dismissals, such as the level of compensation for severance. This continued legal uncertainty makes it difficult for firms to respond rapidly to the changing circumstances of the Japanese business environment. This also has an adverse effect on the investment environment, as firms hesitate to restructure their operations for fear of potentially adverse legal consequences. It would be helpful to clarify the rights and responsibilities of employers and their employees in restructuring and dismissal situations in further guidelines.

Concerning pension schemes, the refunds on mandatory contributions to Japanese pension plans paid by expatriate employees are currently capped at a maximum of 3 years/1,416,000 yen for departing expatriates, the rest being simply confiscated. This significantly limits the incentive for expatriates to engage in a professional activity in Japan with a long-term perspective. Expatriates affiliated with foreign-based pensions plans are assessed on the contributions made to such plans on the basis that a benefit arises at the time of contribution, despite the fact that such benefits are likely to be taxed again upon retirement.

Regulations governing temporary workers have seen significant progress. Recent revisions to the Labour Standards Law have increased the number of job categories for temporary (or dispatched) workers including, for the first time, jobs in the manufacturing sector. The 3 year limit on temporary employment has been eliminated for 26 different job categories, and the allowable employment contract period has been increased from 1 year to 3 years for others. In particular, lifting the ban on the manufacturing industry was a significant step forward. The EU encourages Japan to pursue this process and to lift also the restrictions that remain for recruitment agencies (whether for permanent or temporary jobs) and interim employment agencies (or temporary staff despatching agencies, *haken gaisha*), in particular in the area of construction and port transport.

The EU also notes an urgent need to encourage foreign investment by relaxing residence and immigration rules and accelerating related procedures, such as visa rules, work permits and other stay-related requirements, including for transfers within companies. The EU supports the recommendations of the JIC's expert committee to this end. Keidanren also pointed out the urgent need to simplify and accelerate procedures for visas, work permits and other entry and stay-related procedures (so as to provide access to the best human resources companies can get, regardless of nationality).

Priority reform proposal:

a. The EU suggests to clarify further regulations governing employee dismissals so as to enhance management flexibility and operational efficiency. Specific rules defining acceptable grounds for dismissal for economic reasons should be introduced.

b. Concerning pension schemes, the EU suggests to
   (i) Improve the defined-contribution (DC) pension scheme by increasing tax-exempt contribution levels, allowing matching contributions, and allowing plan-holders to borrow against their pension reserves.
   (ii) Allow for a full remittance of mandatory contributions to the Japanese public pension system to departing expatriates and their employers.
   (iii) Make contributions to foreign-based pension plans subject to the same tax relief as contributions made to pension plans in Japan.

c. The EU continues to request the lifting of restrictions on the remaining job categories which can be handled by recruitment or interim employment agencies.

d. A relaxation of the rules and procedures related to immigration and residence status should be considered.

1.2. Government procurement

In 1999 the Government of Japan awarded 580 contracts of above 6.7 million euro each in value for public works and public construction, amounting in total to 7.8 billion euro. Only two of these contracts were awarded to foreign companies, a total amount of 13 million euro. No EU construction company was awarded with public works contracts in Japan in 1999 (or indeed in 1998 - these are the latest figures available to the EU).

The WTO Agreement on Government Procurement provides access to EU companies for public construction contracts in Japan. Despite the value of this sector and the significant amount of works falling under the scope of this Agreement, European companies continue to be effectively excluded from this sector. The European Union looks forward to a specific dialogue with the Japanese Government on the reasons for this disappointing situation and, amongst other issues, on how to simplify the qualification system for public works and public construction in order to make public works and public construction tenders more accessible to foreign companies.

EU companies are handicapped by low transparency in the procedures for calls for tenders, in particular those launched by local authorities. The criteria for evaluating tenders are not very detailed, while juries are not very qualified technically and seldom read the files. Often, the principal is interested in the technical features of the projects, rather than in the performance expected of the proposal, however clearly these are explained in tender bids. This lack of clarity opens the door to informal discussions between the contracting body and the tenderers, and therefore to serious distortions of competition. It contributes to maintaining a *status quo* which hinders new market entrants and constitutes a *de facto* obstacle to market access.

According to a recent survey on the new partnership between public and private sectors in public works and services (The Survey on Actual Conditions Regarding Access To Japan, July 2003) conducted by an advisory council to JETRO, there had been a total of 100 PFI (private finance initiative) projects as of April 2003. In only three of those did consortia with foreign participation made a bid, and only one was awarded. According to the survey, it is hoped that the promotion of entry into Japan by foreign companies with experience in PFI and PPP (public private partnership) will "shake up the outdated market and trade practices, and in turn lead to greater efficiency and revitalization of society and the economy." The survey confirms many of the requests previously made by the EU. It identifies 23 issues, focussing on (i) requirements for bid participation, (ii) bidding, (iii) screening, and (iv) contracts. In all of these areas, the survey demonstrates a large gap between Japan and other countries in the institutional aspects and business practice. Issues at stake include the business evaluation system, ranking, and past experience in Japan. The common use of ceiling price systems raises the cost of preparing for a bid, and the lack of transparency in bidding evaluation criteria makes it difficult to forecast the possibility of winning a project. These issues are part of the explanation as to why many foreign companies see little appeal in PFI projects in Japan.

Observations made by European companies who participated in various tender procedures give rise to the following comments:

- It still seems difficult, if not impossible in many cases, to have international references and experience recognised as equivalent to business experience in

Japan. Some companies are not aware of the need or indeed the possibility of having their overseas experience certified as equivalent by a Japanese ministry.

- Restricted tender procedures include a "pre-qualification screening", where certain participants are already judged to be non-eligible without further justification. The absence of external and independent experts on the screening board is often noted. (The circular dated 31.10 2002 issued by MLIT to encourage local authorities to use outside expertise for technical evaluations may have a beneficial effect.) Companies also note a lack of explanations as to why certain bids are chosen or refused.

- In many cases, specifications are far too narrow and do not allow bidders to express added value in their bids and to offer creative solutions. This also makes it virtually impossible for a company to launch a successful bid if it did not actively lobby during the pre-project stage, possibly by influencing the technical parameters of the tender specifications. In some cases, the specifications are "tailor-made" to fit the product/service range of certain domestic competitors, thereby effectively excluding alternative technical solutions. Indeed, in many cases the real competition takes place at the pre-project level, before the specifications are determined.

- The requirement to sustain a local office or a site representative (for projects worth 5 million Yen) adds to the costs. Also, the requirement to maintain a local production facility makes participation for foreign bidders in some cases impossible, in particular for smaller companies.

- Foreign bidders often bring a significant price advantage as a major asset into tender procedures in Japan, if only because they can tap into more cost-efficient resources from overseas. However, it appears that, in some cases, this price advantage is effectively neutralised during a tender procedure by (i) giving relatively little weight to price as compared to technical aspects, and by (ii) using certain reference price calculations which have as their effect that the points awarded for the price evaluation are virtually the same for all bidders. For the foreign bidders, their major advantage is lost. It also means that the public entity organising the tender will, more often than not, be faced with a winning bid that may be much higher priced than other alternatives. A possible solution in such cases might be to proceed in a staged process; with a technical evaluation first, and then with the opening of the bids and price negotiations with the best-placed companies.

In the European Union, the body of European rules as regards public calls for tenders is compact and detailed (directives on work, services and supplies in force for approximately ten years). The EC Directive for the award of public works contracts (93/37) provides the framework for qualitative selection in Articles 24 to 29 to be used for each work contract award procedure. These provisions ensure the necessary degree of harmonisation amongst the national laws in the EU. Unlike the Japanese system of business evaluation (*keishin*), the official lists of recognized contractors referred to in article 29 of directive 93/37/EC do not constitute exhaustive lists of suppliers that have the right to participate in contract awarding procedures. Moreover, for non-domestic suppliers, registration in the official lists cannot be a precondition for participating in contract awarding procedures. Finally, in the European Union, contracting authorities, when they determine the financial and economic standing and the technical capability required for a contractor to be eligible, must specify in each

contract notice or invitation to tender which references are to be produced. Those references must be non discriminatory and limited to those which are essential to ensure a company's capability to perform the contract in question. In any case, the European Commission, as a guardian of the EC Treaty, may take the appropriate measures to ensure respect for the principle of non-discrimination for reasons of nationality. It subjects all parties, governing body and competitors, to precise and rigorous procedures.

Priority reform proposals:

1. *Increase transparency and predictability on the qualification criteria and harmonise them with the so-called "business evaluation" (keishin) system of qualification conducted annually;*

2. *Modify the "business evaluation" (keishin) by introducing a system more closely related to the concrete work/construction to be conducted;*

3. *Introduce transparency and objectivity in the classification of categories of works and in the criteria for classification of works under a given category;*

4. *Progressively introduce harmonised guidelines for procurement in all public works and construction, including standard forms for bids and contracts.*

5. *The main focus should be the simplification of qualification, predictability and non-discrimination against foreign bidders. It is proposed in particular to :*
   - *(i) Ensure that overseas experience of foreign countries is duly taken into account without complex government recognition systems in the business evaluation, including proven experience on the part of subsidiaries and mother companies;*
   - *(ii) Harmonise as much as possible the "business evaluation / keishin", construction licenses and qualification requirement for each project.*
   - *(iii) Promote harmonised criteria in the "business evaluation" (keishin) amongst the different procuring entities.*
   - *(iv) Introduce a more predictable and automatic mechanism in order to determine an enterprise's technical capability to perform a project.*
   - *(v) Improve the transparency of the procedures (clearly posted selection criteria and weighting, publication of the results of the evaluation);*
   - *(vi) Ensure the professionalisation of the evaluation and independence of the evaluator.*

1.3. Journalism: freedom and equality of access to information

Access to press conferences, briefings and other media events in Japan organised by official bodies (from central government ministries through prefectural governments to local police headquarters) is generally restricted to the membership of that body's *kisha club*. The innumerable *kisha clubs* in Japan club usually consists of a room provided by the body concerned on its own premises, which is shared by the journalists belonging to the club and functions in practice both as their office and as a briefing venue.

With the exception of a limited number of wire services (which, if they are members at all, often have only associate membership and therefore can listen but have no right to ask questions), membership is generally denied to journalists from foreign media organisations. Even where membership is open, it is not realistic to expect foreign correspondents (often the sole representative of their media organisation in Japan) to maintain memberships of the many *kisha clubs* they would have to belong to in order to cover breaking news stories. It is worth noting that *shukan-shi*, or mass circulation weekly magazines, as well as other weekly, monthly or bi-monthly magazines are also excluded, as well as specialised press covering sectors other than those directly relating to the host body. Membership matters, while ostensibly in the hands of the hierarchy of the club in question, are in fact closely controlled by the host body, with which the club has a symbiotic relationship. Club members are in constant physical proximity to their briefers and thus also enjoy privileged access to off-the-record information.

There have been numerous instances where restrictions on foreign journalists' access, including the *kisha club* system, have impeded reporting outside Japan of events of widespread international interest and significance. Examples include the Lucie Blackman illegal killing case and last year's visit to North Korea by PM Koizumi. By denying foreign correspondents first-hand access to briefings, the system acts as a *de facto* competitive hindrance to foreign media organisations. It unfairly makes them slower to bring information to their audience than domestic organisations, and, unable to put questions on the spot, forces them to rely on second-hand information. In effect, the system works as a restraint on free trade in information.

The system also has broader negative consequences for both the domestic and international consumer of information about Japan:

- Officials and the hierarchy of the *kisha club* have the means to prevent the spread of information they may consider disadvantageous, on pain of exclusion of the offending journalist from the club. The system thus acts against the public interest.

- By giving both officials and journalists a vested interest in maintaining the exclusivity of a story, the system encourages over-reliance on a single source of information and a lack of cross-checking, thus diminishing the quality of information available to the wider public.

- The system encourages the widespread and undesirable practice of split briefings for domestic and foreign journalists, increasing the potential for information to be tailored to one or the other audience by the briefing party, and exacerbating the risk of spreading inaccurate and biased information about Japan.

Similar arrangements in the EU, like the UK's Westminster lobby system, have been abolished in favour of open and equal access for domestic and foreign media, largely based on the recognition that such systems are an impediment to making the government's message as widely available as possible. These considerations are especially relevant at a time when the Japanese government is seeking actively to spread its message on issues such as increasing inward FDI. Limited progress has been made by Ministries such as MOFA, which has begun to notify journalists (including foreign journalists) of press briefings in advance and has undertaken to publicise the role of the MOFA press card to other Ministries and organisations.

Prefectural governments such as Nagano and city governments such as Kamakura have shown the way ahead by breaking the links of exclusivity between themselves and the relevant *kisha clubs*, and opening press events to all interested parties. It is fully within the power of Ministries and other organisations to set an example by withdrawing the privileged access rights accorded to the respective *kisha clubs* and setting an example by taking the role of hosting and publicising briefings (for the foreign press, via e.g. the Foreign Press Centre) directly into their own hands and out of *kisha club* control.

The disservice being done to consumers of information by the *kisha club* system can only be addressed by its abolition in the interests of fair and equal access to media events for all media organisations, domestic and foreign. In any case, all holders of a Ministry of Foreign Affairs press card should have the right to attend media events organised by official bodies on an equal footing with domestic journalists. Legitimate problems with numbers of attendees can easily be dealt with through the existing pool structure - the FPIJ, or Foreign Press in Japan - which was itself created at the behest of the Japanese government to deal with just such situations.

Priority reform proposals:

a. Accept the Ministry of Foreign Affairs press card issued to correspondents of foreign media organisations as accreditation for all media events held by Japan's official bodies, to enable access on an equal footing with all domestic journalists.

b. Remove the restraint on free trade in information by abolishing the kisha club *system.*

1.4. Information society

Recent developments in the telecommunications sector in Japan include:

The bill to amend the Telecommunication Business Law (TBL) which was submitted to the ordinary Diet session in March 2003 was adopted on 17 July and promulgated on 24 July. This amended TBL does not require in principle the notification of tariffs for certain services, and incorporates the elimination of the business distinction between Type I and Type II. The date of its implementation will be decided by ministerial ordinance, but it is expected to be enforced in spring 2004.

Five major Japanese telecom companies (KDDI, Japan Telecom, Cable & Wireless IDC, Fusion and PoweredCom) have sued the MPHPT over its approval to raise NTT's interconnection rates (17 July 2003), on the grounds that the MPHPT has failed to respect its own policies, processes or international best practice (*on the issue of regulatory independence, see EU proposals a. & b below).*

The EU notes that in 2003 Japan has initiated further reforms for the regulation of the Information Society and in particular the removal of the distinction between type I and Type II licences as well as the removal of the requirement for the filing of tariffs currently applying to both designated and non designated carriers for certain services. The EU welcomes these initiatives and considers that they could contribute to the improvement of competitive conditions in Japan provided that certain conditions outlined below are fulfilled.

The EU considers that some progress still needs to be made to ensure that the regulatory framework is technologically neutral regarding the rights and obligations applicable to designated carriers in all market segments, that the regulator is independent and not accountable to any service supplier, and that the notion of joint dominance is recognised in the regulatory framework in Japan.

The EU also recommends that particular attention be paid to: (i) the establishment of a list of product markets to assess the level of competition and identify designated carriers, (ii) the clarification of the conditions under which designated carriers have the ability to affect terms of participation in the market, and (iii) the prevention of anti-competitive practices by designated carriers.

Priority reform proposals:

a. The telecommunications regulatory authority should be fully independent from business suppliers, impartial, and devoted to the promotion of competition in the Japanese market. It is important that the legislative texts show clearly that the regulator is only in charge of regulation (promotion of competition, universal service, licensing …) and does not interfere in the management of an operator. The EU therefore considers that the NTT law should be repealed since all necessary regulatory controls should be carried out on dominant suppliers or providers of universal service pursuant to the Telecom Business law (amended accordingly) and State/Public Sector shareholder's must not be treated in the telecom sector differently from that in other sectors.

b. *The application of the LRIC model on interconnection should be reviewed in order to correct the misallocation of non-traffic sensitive elements which results in higher costs for NTT-E&W's competitors. Similarly, the settlement mechanism which has been established to compensate the potential losses of revenues incurred by a reduction of traffic should be abolished. The recent revision of NTT's fixed interconnection charges raises serious concerns from both an economic and a regulatory perspective and notably with regard to the impartiality of decisions taken by the regulator in Japan.*

c. *Establish a technologically neutral regulatory framework for electronic communications services so that designated carriers operating services in the local and/or long distance wire-line markets as well as in the wireless market can be subject where appropriate to the same rights and obligations, notably in relation to the prevention of anti-competitive conduct and interconnection. Indeed, the designation of dominant carriers should be made possible in all service markets (including the long distance wire-line market) on a technologically neutral basis. It should be based on the ability to affect terms of participation in the market and not on specific criteria set* a priori *(as is the case in the mobile market).*

d. *The designation of carriers having the ability to affect terms of participation in a market should be subject to a competition investigation* inter alia *in the long distance and mobile markets before regulatory obligations apply. An indicative list of relevant product markets should also be published. The establishment of a study group to review of the state of competition in telecommunications market in September 2002 seems to be an initial step in that direction but it also confirms adversely that such competition investigations in both the long distance wire-line and in the wireless markets have not so far been established. Therefore, the EU considers that, the basic architecture of the current regulatory framework in Japan, and the subsequent decision not to designate for instance NTT-CC is not based on transparent, objective and non-discriminatory criteria. All tools to correct market failures should be made available by the law for dominant operators in any relevant market, and the law should not* a priori *distinguish between technologies in that respect. Regulatory measures to correct market failures should address effectively such failures.*

e. *The notion of joint dominance should also be recognised in Japan's regulatory framework as it is currently not so recognised in the revised TBL.*

f. *Wholesale and retail tariffs notification requirements should be maintained for carriers with significant market power and/or having control over essential facilities. The most recent revision of the TBL, by lifting the obligation of Type I designated carriers to file tariffs for wholesale and retail prices prevents the regulator from monitoring the pricing conduct of the dominant carriers and to ensure that they do not engage in predatory pricing behaviours. Pursuant to the new revised framework in Japan, Type I designated carriers could thus for instance discount selectively in order to damage their competitors, or enter into price squeeze strategies. The EU understands that tariff notification and accounting separation obligations will continue to apply for services categorised as "Universal Services" for all operators including non-dominant operators.*

Consistent with the principles of asymmetric regulation and proportionality, the EU considers that these obligations should be lifted for carriers which are either

non-dominant or not selected as universal service providers since it impacts their ability to compete effectively against designated carriers and causes them to incur undue cost. It also involves unnecessary procedures to the detriment of a fair and effective competitive environment.

g. *Universal service should be adequately implemented, only where necessary, in order to address costs that are not covered by normal commercial practice. The objective of getting uniform rates nationwide in Japan should be achieved through the establishment of a universal service fund and should, in particular, fulfil the principles of transparency, non-discrimination and competitive neutrality. The cost of providing universal service to ensure uniform rates nationwide (including in less profitable areas) should instead be based on LRIC while the benefits of providing universal service (network externalities, brand name and presence) should be fully taken into account in the computation of costs. The current averaging system between NTT-E&W is a matter for concern since it leads to cross-subsidies between NTT-East and NTT-West, although the two companies are structurally separated and in principle prevented from entering into such practices through the imposition of competitive safeguards to ensure an adequate separation of their accounts. As a result, interconnection charges are also no longer cost-oriented.*

h. *Harmonise spectrum allocation for the additional IMT-2000 bands (especially 2.5GHz band) and bands for post 3G mobile communication systems.*

1.5 Financial services

1.5.1. Insurance sector

Insurance market deregulation in Japan has made progress in recent years. Extending the scope of the notification system for new products (sometimes called "file and use", but in fact a simplified form of the prior approval system), for instance, is most welcome. However, product and rate approval requirements have been maintained, and, in the interests of efficiency, competition and consumer choice, the EU therefore continues to seek further genuine and effective deregulation of the Japanese insurance market.

As long as individual product and rate approval is maintained, competition will be stifled and the level of economic regulation will be administratively burdensome for insurers, delaying delivery of innovative products to consumers. Even relatively small changes to policy wordings are often treated as if approval was being sought for a new product. The move away from the concept of product approval for most commercial products represents a positive step, but it should be extended to all lines of insurance. Micro-level individual product and rate approvals should ultimately be fully abolished and replaced with macro-level prudential measures regarding the solvency margins and capital adequacy of insurance companies, in keeping with the principle of moving from *a priori* regulation and supervision to *ex post facto* checking and scrutiny. Consumer protection does not require an approval-in-principle system, and can be ensured through specific and adequate prudential measures, such as publication of the terms and conditions for the products, including rates and details of the liable person, as well as anti-trust safeguards. In any case, the file and use system should be applied to all insurance products that are sold to sophisticated commercial buyers, as these policyholders do not need such far-reaching consumer protection measures as individuals do.

The need for repeated and costly replenishment of the Policyholders' Protection Fund could also largely be avoided were more thorough macro-level supervision of insurers' fundamentals in place. An adequate prudential regulatory system based on the financial solidity of the insurer rather than product control would enable timely intervention by the regulator to prevent company failures, through restructuring if necessary, and avoid moral hazard for poorly managed companies at the expense of better-managed companies. The Policy-holder Protection Corporations' (PPC) funds should be called on only as a last resort. This would also help to avoid the uncertainty in the business environment caused by constant reassessment of companies for contributions.

In principle, public sector entities such as *kampo* should not be engaged in the creation of any new products that could be provided by the private sector. In order to ensure a level competitive playing field, both *kampo* and *kyosai* (insurance business for co-operative societies) should be subject to the same regulatory oversight, capital, solvency margin, taxation and policyholder protection funding requirements as private insurers. Furthermore, the EU understands that *kampo* is in the process of trying to introduce a new "whole life" insurance product (known as "whole life with term rider"). This product is so structured as to compete not only with "whole life with term" products, but also with sickness insurance products. This is because after the term rider expires, the product is almost identical to so-called "third sector" products, which are at the very core of European and US insurers' business operations

in Japan. *Kampo*'s enormous size (holding 88.5% of the total 142.1 trillion yen assets in the Japanese private life insurance sector) and its government guarantee are thus being used unfairly to leverage its competitive position vis-à-vis private products in a hitherto highly competitive sector. There is thus ample and legitimate private sector concern that the increased managerial independence of the Postal Services Public Corporation (PSPC) will be used to develop further new insurance products. The EU believes that the PSPC should not be involved in any such new underwriting activity, and that the Japanese government should not approve *kampo*'s proposed new products.

Finally, the brokerage system has not been liberalised in practice. This encourages intermediaries to remain as agents and denies customers access to professional, independent advice. Brokers are not currently allowed to work with agents nor are they allowed to collect premiums on behalf of their clients. In other major insurance markets, brokers are able to compete with agents in the same lines and are allowed to work with agents in the distribution and sales process. Japan is requested to align its practice to conform to international standards. The Financial Services Agency (FSA) should commit to creating a modern brokerage system under which brokers are granted direct and effective access to the insured, and are allowed to collect premiums from policy holders. Brokers should have the right to submit their tailor-made policies directly to FSA, and not via an insurance company. This activity should be understood as distinct from actual underwriting activity, which is not the responsibility of brokers. Excessive requirements which hinder the development of the insurance brokerage sector in Japan, such as the disproportionate compulsory legal deposit, cumbersome administrative and processing issues including the time limited validity of brokers qualifications, should be addressed.

Priority reform proposals:

a. *Abolish product and rate approval for insurance products by completing the move to a notification system. This is crucial in order to allow services suppliers to operate on a commercial basis. The file and use system should be extended to personal lines. In addition, the processing period should be reduced to 30 days. We welcome the adoption of a notification for non-life insurance. We would encourage the Japanese to do the same for life insurance.*

b. *The EU urges Japan to move over time to a system of regulation based on solvency ratios and overall financial stability comparable with international practice. The EU urges Japan, in the course of the current review of policyholder protection arrangements, to give priority to finding a solution based primarily on macro-level oversight, with a company-funded safety net (Policyholder Protection Corporation) available strictly as a last resort only.*

c. Kampo *and* kyosai *should be made subject to the same regulatory regime as licensed private sector insurers, and should refrain from taking advantage of their privileged regulatory and taxation position to develop new underwriting activities.*

d. *Remaining restrictions on the sale of insurance products through financial institutions should be abolished (see also banking, below).*

e. *Modify the legislation and regulations on brokerage in order to allow brokers to work with agents and to engage in the collection of premiums, as a normal*

part of their activities. Brokers should also be allowed to submit their tailor-made policies directly to FSA, and not via an insurance company, bearing in mind that brokers are representing industrial and sophisticated commercial clients rather than private individuals.

1.5.2. Banking and securities

European securities firms are by and large part of a larger banking group. Article 65 of the Securities and Exchange Law forbids securities firms to conduct banking transactions and banks from conducting securities transactions without establishing a subsidiary. This necessitates a duplication of functions which increases costs for the consumer and the financial group alike. Furthermore, industry reports that firewalls legislation is more strictly enforced for wholesale than retail operations, thus even running counter to the original purpose of already obsolete legislation, and creating further regulatory inconsistencies. Financial groups should be allowed to operate as an integrated business in the banking and securities sector. Again, consumer protection concerns can be dealt with through proper prudential legislation.

The Financial System Reform Law of 1998 allows banks to conduct insurance business through subsidiaries as from October 2000. Revision of the Insurance Business Law in 2000 made it possible for banks to engage in retail sale of certain kinds of insurance products from April 2001. While these changes are welcome they do not meet the requirements of universal banking. Establishing subsidiaries is a lengthy and expensive process which acts as a market access deterrent, as do limitations on the scope of insurance products that may be sold by banks. Furthermore, the requirements such as stipulating that all staff dealing with customers in a bank branch selling insurance products are licensed to sell insurance products even if only one or two staff actually engage in selling them is too burdensome. Any consumer protection concerns can be adequately dealt with through proper prudential legislation. As a first step, all restrictions on the sale of insurance products through other financial institutions should be dropped.

As in the asset management sector (see below), there is considerable overlap of functions between government regulators (FSA, SESC, etc.) and self-regulatory organisations (e.g. Japan Securities Dealers Association, Tokyo and Osaka Stock Exchanges, etc.). This increases the regulatory burden on banking and securities firms by duplicating supervision, inspection and reporting requirements and hinders efforts to increase the transparency and fairness of the regulatory regime. The EU proposes that duplication of functions should be eliminated and reporting requirements streamlined.

Priority reform proposals:

a. Abolish the provisions of Article 65 of the Securities and Exchange Law which prohibit integrated management of banking and securities businesses.

b. Abolish the restrictions which prevent insurance products from being distributed via financial institutions such as banks and securities firms. Allow universal banking (covering insurance, banking, securities, and asset management).

c. Create a streamlined and clarified regulatory regime for the banking and securities sector, removing the duplication of regulatory functions between governmental and self-regulatory bodies.

1.5.3. Asset management

Much has been achieved in terms of opening the Japanese pension funds market to Investment Advisory Companies (IACs). Most recently, on 4 July 2003, the Diet approved a revision to the Postal Services Public Corporation (PSPC) Law, allowing IACs access to some ¥360 million of *yucho/kampo* funds. However, practical rules on how IACs are to have access to the management of these funds have not been made public, notably whether selection will be on the basis of open tenders with clear rules.

It would be in the interest of Japanese pensioners, investors and the financial services industry, for regulations governing the asset management sector in Japan to be clarified and simplified in order to put the emphasis on macro-level prudential regulation, and eliminate needless duplication of regulatory effort.

Separate legal and regulatory requirements covering the management of investment trusts and that of investment advisory services unnecessarily duplicate licensing, filing and customer disclosure requirements at no gain to investor protection and to the detriment of consumer choice. Promotion and distribution of the products of group affiliates, as well as dealing on their behalf, are normal activities permitted in other major markets and should be allowed also in Japan. In particular:

- A single, harmonised regulatory regime should be established for the asset management sector.
- The sale and marketing of funds outside Japan managed by affiliates of the same financial groups is a core business activity and should not require a cumbersome additional side-license. It should also be permitted for feeder funds regulated in Japan to be invested wholly in a single offshore vehicle. Furthermore, the EU is concerned that new tax rules may discriminate against investment products domiciled outside Japan.
- As in other markets, asset managers should be able to place orders to buy or sell on behalf of group affiliates without having to hold a securities licence.
- Rules on the calculation of Net Asset Values (NAV) should make it clear that they need to be calculated only once, independently of the asset management company, rather than twice (i.e. by both the investment trust managers and the trust bank holding the assets), as is now the case. Investor protection is better served if trust banks perform a true trustee function and take sole responsibility for asset value calculations.

Priority reform proposals:

a. *Operational rules for access of IACs to discretionary management of* yucho/kampo *funds should allow open and transparent competitive tendering and be made available beforehand for public comment by all interested parties.*

b. *(i) Create a single, simplified and clarified regulatory regime for the asset management sector. Remove costly and cumbersome regulatory requirements such as (ii) the side-business licensing still needed to promote and distribute products on managed by group affiliates outside Japan and (iii) the need for a securities license to deal on behalf of affiliates. (iv) Allow feeder funds to invest wholly in a single offshore vehicle. (v) Remove the unnecessary duplication of NAV calculations by obliging Net Asset Values (NAV) to be calculated by the trustee, independently of the asset management company.*

1.6. Postal services

Japan Post was inaugurated on 1 April 2003, taking over the three postal services of mail delivery, postal savings and *kampo* life insurance from the Postal Services Agency. The establishment of the new public corporation, based on the Basic Law on the Administrative Reform of the Central Government enacted in 1998, marks the first step in privatising the nation's postal services. The three services operate under a single management but on a self-supporting basis, with a corporate-accounting system and other private-sector business methods for better operational efficiency. On 11 July 2003, Prime Minister Koizumi said in the House of Councillors' Budget Committee that he planned to privatise postal services in April 2007, referring - for the first time - to a concrete timetable.

The EU welcomes the ongoing reform of postal services, towards a more open domestic postal market, allowing other firms than the incumbent operator to offer postal services, to the benefit of customers. This places its development in line with similar trends world-wide, and with Universal Postal Union (UPU) recommendations. But two points of concern remain.

The first point concerns regulatory independence. Japan Post - as a public corporation - continues to be regulated by MPHPT who also retains ownership. The EU would suggest to mark the clear separation between the governmental role to regulate the postal services market and the ownership rights by establishing an independent regulatory authority so that conflicts of interests can be avoided.

The second point may be an illustration of the need for regulatory independence. The traditional focus on ensuring universal service by postal operators seems to outweigh the political will to establish effective competition in the postal market. On 1 April 2003, the mail delivery market, previously monopolized by the Postal Services Agency, was opened to limited competition. However, owing to strict conditions on operators, no companies have so far entered the business. Article 24(2) of the MPHPT Ordinance for the Law concerning Collection and Delivery includes such requirements as the establishment of a nationwide network of post boxes (sashidashibako). For the time being, therefore, customers thus can hardly expect benefits such as cost reductions through competition.

Priority reform proposal:

a. In the context of the ongoing reform of the postal sector, the Government of Japan should aim at ensuring the independence of the regulator.

b. The service obligations and requirements for the mail delivery service should be set in a way that allows effective competition by new entrants.

1.7. Transport

1.7.1. Air transport

Bringing together people from Japan and the EU is one of the main elements of the EU-Japan Action Plan. Furthermore, it is an explicit objective of the Japanese government to double the number of foreign visitors to Japan by 2010. However, the desired increase in inward tourism to Japan can only be achieved by removing the existing obstacles for international air transport. Air services are a crucial input factor for trade between EU and Japan and especially for the development of international tourism. The provision of such services is therefore vital to the economies of both Japan and Europe. It is necessary to allow for high frequencies of air transport between Japan and the EU in order to facilitate an increase in trade flows – especially of high-value goods – and tourist movements.

Narita airport is the only airport in the Tokyo Metropolitan area open to international scheduled services. As a consequence, transparent and non-discriminatory access for Community airlines to Narita airport is crucial for further developing air transport links between Japan and the EU. Narita slot capacity does not meet the demand and this scarcity creates a serious bottleneck effect on the development of business and tourist relations between Japan and third countries. We acknowledge some improvements with regard to slot capacity, particularly with the opening of the new 2180 m "B" runway in April 2002, and also transparency of slot allocation. However, the current situation for EU airlines leaves still considerable room for improvement.

We welcome MLIT's recently announced plans to create more flexibility so that Haneda Airport can be used for international flights. However, according to our information Haneda will be opened only for short-haul charter flights. It would reduce the capacity bottleneck in the Tokyo region significantly if Haneda Airport were opened to all on a transparent and equitable basis for international long-haul flights in the future.

Improvements to the transparency of slot allocation appear to have been made. However, there is still considerable potential to simplify and enhance the transparency of regulations and to modify regulations to conform to the IATA guidelines that represent the international standard.

Airport charges and air navigation charges in Japan are the highest in the world. The high level of charges deters airlines from increasing frequencies for flights between the EU and Japan. In spite of the current crisis affecting the civil aviation industry and the substantial traffic losses in East Asia due to SARS, Japanese airports did not follow the example of other East Asian airports by reducing airport charges. The pricing of Narita Airport Authority (NAA) should be closely monitored in order to prevent excessive charges. The privatisation of Narita Airport will allow the airport to diversify into other business like retailing, and NAA President Masahiko Kurono has already announced his intentions to lower landing fees in the future. MLIT should encourage the responsible authorities to reduce charges as early as possible. An independent regulatory regime should ensure that charges are just and reasonable. More competition for the provision of airport-related services such as ground handling could further improve the situation. (a recent report from October 2002 shows how this has been done in the EU since 1997).

The pricing of international air fares in Japan and the ways in which they may be publicised and settled in that country are all matters of deep concern to the airline industry as a whole. Airlines should be allowed to sell fares at market levels directly to consumers, and without the need for additional consultation with MLIT. Equally, the problem of a complex system of reimbursements to travel agents for tickets discounted beneath the government-approved prices remains and prevents airlines from selling discount fares directly to the customer.

Priority reform proposals:

a. *Arrangements for the setting of official prices in Japan for international airfares should be further liberalised so as to reflect the reality of the market. The ways in which these fares may be publicised should permit airlines to quote real market prices directly to the consumer. Arrangements for the settlement of bills in Japan for international airfares should be simplified into a single operation if that is what the parties desire.*

b. *In line with the objectives of the reform exercise, the EU urges the Japanese authorities to take the necessary steps to avoid any unnecessary rigidities or bottlenecks in the allocation of the runway capacity available at Narita, particularly after the opening of the second runway. This includes maximising the overall capacity by promoting the use of the longer runway by long-haul services, which cannot be transferred to the new runway. Transfers of short-haul services to the new runway should be further promoted, if necessary by mandatory schemes.*

c. *In addition, in order to meet market demand for landing and take-off slots at Tokyo's Narita Airport, the current regulations which limit their numbers should be revised so as to permit an increase in the total available for allocation.*

d. *The allocation of slots at Japanese airports should be carried out in accordance with a transparent, fair and equitable slot allocation system, taking into consideration IATA guidelines. Allocation procedures at Japanese international airports should be subject to critical regulatory reform in order to give the slot co-ordinator the freedom to respond more readily to market demand while taking into account operational restrictions applicable at the airport.*

e. *The Japanese authorities should encourage the responsible entities to decrease landing charges at Japanese international airports, fees for navigation in Japanese airspace, and charges applied for the use of communal spaces at Japanese international airports to levels that correspond better to the current market situation. The government should ensure that the decision to privatise Narita airport does in fact benefit airlines, passengers and shippers as well as the airport.*

1.7.2. Sea transport (International shipping)

There has been progress in Japan in terms of operating hours at major ports. Industry reports that all major ports regularly frequented by international container shipping lines are now operating on a 24-hour basis.

The remaining problems faced by the European shipping industry in Japan arise from restrictive working practices on the waterfront. These practices limit competition and operational flexibility and raise the costs of doing business. The newly announced "super hub port" strategy of the Ministry of Land, Infrastructure and Transport (MLIT) seeks to reduce costs by as much as 30% through selecting certain ports where container handling activities would be concentrated and charges and rents reduced. This welcome policy represents a recognition that costs at Japanese ports – amongst the highest in the world – have been critically undermining their competitiveness via-à-vis other ports in East Asia, to the detriment of domestic and foreign users in Japan. Clearly, removing constraints on competitive conditions for the provision of stevedoring services will be essential if cost-cutting targets are to be met. Another issue is the selection of which ports are to be designated as "super hubs". It would be logical for MLIT to involve foreign shipping lines, which after all carry over 60% of Japan's international containerised trade in and out of the nine main ports, in the selection process.

High port costs can have significant knock-on effects for the rest of the economy. The shipping industry is now recovering from a period of overcapacity. In fact, following a pick-up in global trade, capacity is now in heavy demand. In such a situation, shipping lines' attempts to maintain the same charges for Japan-based customers as for the rest of Asia are likely to be frustrated as priority will naturally be given to customers in countries with lower-cost ports where margins are higher. This can lead to Japan-based exporters having difficulty getting access to capacity when and where they want it, or to them having to pay a premium to do so.

The situation regarding the Prior Consultation System in Japan remains substantially unchanged. The Japan Harbour Transportation Association (JHTA) has an agreement with relevant parties to hold consultations with shipping lines prior to any changes that might reduce employment or adversely affect working conditions. Shipping lines are therefore required to consult the JHTA for approval of certain changes to their operations, including even minor issues such as substitution of vessels.

While there have fortunately been no serious difficulties so far with the Four-Party Agreement now in force, the large discretionary power of the JHTA and the *de facto* restraint this exercises on free competition in harbour service provision, are anomalous. The system continues to inhibit the development of competitive pressures which might push charges down. The current situation is based solely on good will. Whether or not, as MLIT contends, the number of cases handled through the JHTA has dropped by 95%, the existence of the JHTA's powers in practice inhibits shipping lines from seeking out competitive bids for port services.

The JHTA fulfils an obsolete regulatory function while also representing the interest of only one side of the regulatory equation – in this case the domestic port services industry. The EU takes a position of principle that regulatory functions, if indeed at all necessary, should be separated from promotional functions in order to ensure a level playing field for new entrants, promote competition, and avoid conflicts of interest.

The Three-Party Agreement remains, in addition, basically unimplemented. There remains considerable potential to rationalise and simplify regulations as well as to accelerate reform of regulatory procedures in the area of prior consultation. The EU in particular requests MLIT to address proposal (b) below, since it has remained unanswered since first presented.

Priority reform proposals:

a. Ensure that the prior consultation and alternative prior consultation procedures are transparent, equitable and swift.

b. Further review the role of the JHTA in dealing with applications for changes to shipping line operation, with a view to eliminating all vestiges of undue influence on the free play of competition in the provision of harbour transport services in Japan.

2. Reducing the burden of regulation

2.1. Healthcare and cosmetic market regulation

2.1.1. Pharmaceuticals

The European Union acknowledges that the Japanese healthcare system is currently experiencing a period of fundamental change. The availability of affordable, state-of-the-art drugs will benefit the population at large, not only by offering a wider choice at better prices, but also by opening up new ways to cope with present and future health care challenges, such as those inherent to an ageing population.

With the aim of streamlining the consultation and review process, the Organisation for Pharmaceutical Safety and Research (OPSR) and the Medical Devices Evaluation Centre (PMDEC) will be merged. The newly created Agency for Consultation, Registration Review and General Safety Management - an independent administrative agency under the revised Pharmaceutical Affairs Law of July 2002 - will begin operations in April 2004. The agency is expected to strengthen overall safety management of marketed drugs, especially through expansion of its activities in epidemiological research.

The EU applauds the progress made towards reducing the approval time for New Drug Applications (NDA) to twelve months, and notes with satisfaction that NDA approval times have consistently been coming down over recent years. The *kiko* (OPSR) consultation system in the NDA (New Drug Application) process within MHLW has existed for over five years, and the importance of these consultations in speeding up the drug approval process and realising a consistent approach right through from the development to the review stage is increasing.

The EU would like to emphasise the importance of ensuring that the new agency will actually streamline the drug evaluation and approval process and increase the quality of the review system. The new agency also aims to centralise the system for handling drug safety, and the EU supports the pharmaceutical industry in its desire to see that this process does in practice achieve an improved, proactive and consolidated system for drug safety. Furthermore, the new agency should provide improved service reflecting the fees which will be requested of pharmaceutical companies for drug approval applications. One notable positive point is that, in line with EU and US practice, minor changes in drug applications will be accepted without review.

The EU also appreciates the Japanese authorities' greater degree of acceptance of global clinical trial data in approval applications, and hopes that such data will be even more widely accepted by the Japanese authorities in future. Concerns have been voiced by industry about inconsistent implementation of the ICH E5 Guidelines (guidance aimed at facilitating the registration of medicines among ICH regions by recommending a framework for evaluating the impact of ethnical factors upon a medicine's effect), and scientifically questionable arguments made by some OPSR officials, particularly since several years have passed since the ICH E5 Guidelines were introduced, and there have been several successful examples of the use of bridging studies. Discussions on bridging studies between the industry and the Japanese authorities are necessary in order to develop the use of the Guidelines, and to ensure that Japan too can play its part in the global development of new pharmaceuticals.

The biannual drug price revisions carried out by MHLW have now become a target in the context of overall fiscal control and budgetary tightening. It is important to consider further price revisions on the basis of an established policy, and in line with the Vision Statement for the Pharmaceutical Industry issued by MHLW in 2002, with the aim of improving the international competitiveness of the industry.

A note of concern remains also with regard to the manner in which intellectual property rights are protected in Japan. Generic drug manufacturers are still allowed to start developing products before patent expiry whereas the TRIPS Agreement requires protection of such data submitted along with new drug applications.

Priority reform proposals:

a. Further improve the quality and efficiency of the review and consultations process for NDAs, achieve a fully consistent approach right through from the development to the review stage, and ensure that the fees for drug approval will reflect the services offered.

b. Ensure consistent and scientifically well-founded implementation of the ICH E5 Guidelines.

c. Establish a policy concerning the drug pricing system and carry out price revisions based on that policy, while ensuring an appropriate reward for innovative new drugs.

d. Provide an appropriate level of IP protection for new drug applications.

2.1.2. Medical devices

In view of Japan's rapidly aging population, slow economic growth and rising societal expectations for quality of life, innovative health technology can help deliver higher quality health care to the Japanese people. The EU encourages Japan to proceed further in harmonising its regulatory requirements with those of its major trading partners. Further, the EU urges the government of Japan to embrace innovations in health care technologies that allow health care resources to be used more effectively and that will represent an investment in the quality of life and productivity of Japanese patients. Regulatory reform applied to health technologies in Japan should be further promoted to enable beneficial technology innovations to enter the market expeditiously without compromising patient and user safety. To this end, Japan’s active involvement in global regulatory harmonisation activities such as the GHTF, and the adoption of its recommendations, are strongly encouraged.

The EU welcomes the Japanese government’s announcement of its “Vision” for the medical device industry, but wishes to point out the importance of ensuring that pricing and reimbursement policies support the innovation process and are aimed at stimulating continued investment in this field by both domestic producers and importers alike.

Many health technologies are characterised by short product life cycles and high innovation rates. In practical terms, a parallel, rather than sequential, handling of

regulatory approval and reimbursement procedures in Japan could significantly reduce time to market, which is now one to two years, or even longer for a new product. The EU also urges Japan to implement measures to expedite the access, insurance coverage and payment of "new-to-Japan" health technologies, including by accepting cost effectiveness information based on foreign clinical data. Furthermore, linking decisions on domestic pricing and reimbursement levels to those in foreign countries appears discriminatory and is unfair since it ignores the high cost of doing business in Japan, including differences in medical, reimbursement, distribution, and business practices. This can lead to the perverse situation whereby companies may choose not to market their some of their most innovative products in Japan.

Priority reform proposals:

a. *Streamline and improve the transparency of (i) product approval, taking into account world-wide data, and applying sound science and risk benefit assessment, and (ii) post-marketing surveillance systems, notably by ensuring that post-marketing surveillance activity is undertaken by experts with the appropriate expertise in the health technology in question, in a transparent manner. The EU recommends the early adoption and use of internationally recognised standards without additional national requirements.*

b. *Reduce time to market for new health technologies by handling regulatory approval and reimbursement approval in parallel, and further improve access for new products by accepting cost-effectiveness information based on foreign clinical data. Decisions on reimbursement levels should reflect the cost conditions prevailing on the Japanese market.*

2.1.3. Cosmetics

At almost ¥1.5 trillion in value, Japan is the world's second largest market for cosmetics. EU manufacturers have established brands in a market which nevertheless remains dominated by domestic manufacturers. Legislation dating from 2001, warmly welcomed by the EU, has shifted, for most categories of products, the responsibility for product safety towards manufacturers, and largely resembles the European model of a negative ingredient list, limited positive ingredient lists and full ingredient labelling.

However, the new positive lists still contain many differences from those in Europe, and no mechanism has been established yet to bring about their harmonisation. Certain conservation agents, sun filters and coal/tar pigments appear on the EU's positive lists, but are forbidden in Japan. Many companies find that continuing requirements for lengthy safety and innocuity data put them off even attempting to add new ingredients to the positive lists. Such requirements often duplicate tests already performed in the European Union, frequently involve products which have a proven record of safe use in the EU in large volumes over several years, and results in extensive and costly reformulation of products for the Japanese market.

The European Union welcomes Japan's intention to consult further with foreign countries for the purpose of international harmonisation. The EU also emphasises the need for transparency in the application of the new domestic regime with respect to the qualification of ingredients and the implementation of full ingredient labelling.

The "quasi-drug" category used by Japan consists of products ranging from deodorants, hair dyes, hair growers and depilatories, medicated cosmetics (notably whitening agents) and medicated toothpaste to sanitary napkins and over-the-counter health drinks. In practice, the criteria for classification as a quasi-drug are not clear, and it has proved almost impossible to get new ingredients in the quasi-drug category approved (including some ingredients already accepted when incorporated in cosmetics). Pending fundamental reform of this category, a further problem is to overcome the gap between product categories; i.e. products categorised as cosmetics in the EU (and indeed the US), but as quasi-drugs in Japan. Japan has yet to proceed to reclassify a number of quasi-drugs as cosmetics, as is the case for those products in the EU and the US, and in accordance with its announcement in the Deregulation Programme of March 1999.

In view of the ongoing process of progressively replacing animal testing by scientifically-validated alternative methods, the EU also welcomes Japan's confirmation that, in principle, recognition of safety data generated from non-animal alternative testing methods is possible and would welcome information on the applicable guidelines. Mutual acceptance of testing methods would of course be a major benefit of greater international harmonisation.

Finally, the number of accepted marketing claims should be expanded on the basis that the burden of proof of any such claims lies with the manufacturer, with a view to harmonisation with EU standards.

Priority reform proposals:

a. The EU requests that common products such as deodorants, hair dyes, etc. should be regulated as cosmetics. In the meantime, the EU requests a clear statement of which active ingredients qualify a product as a "quasi-drug", and why, and a clarification of the criteria for approval of new ingredients in this category. Useful first steps would include the publication of a nomenclature list, specifications, doses, product categories, and related claims, allowing easier registration of new active ingredients and the use of new cosmetics ingredients, and a move to full labelling analogous to that applied to cosmetics.

b. The EU invites Japan to consult with EU regulatory agencies with the aim of internationally harmonising positive and negative lists, and establishing mutually recognised testing and acceptance criteria for adding new ingredients to these lists and provide official English versions of these lists in order to make them easily accessible to foreign makers.

c. The EU requests Japan to provide information concerning the conditions for acceptance of non-animal testing data on cosmetic products.

d. Allow manufacturers to make legitimate marketing claims on the basis of their responsibility and enable them to substantiate those claims on the basis of methods and practices accepted in the EU.

2.2. Promoting international standards

2.2.1. Recognition of foreign testing/inspection bodies

Conformity assessment plays an important role in ensuring public policy objectives such as product safety, consumer protection and workplace safety. It can, however, place a substantial procedural/regulatory burden on manufacturers and/or importers, particularly if requirements for local and foreign products differ and if conformity is required with regulations under more than one law and under more than one ministry's responsibility. One of the means to reduce this burden - without lowering the protection level that conformity assessment helps to ensure - is to recognise the results of certification activities carried out by approved conformity assessment bodies that can be located locally or abroad. The establishment of clear, even and non-discriminatory criteria facilitates the appointment of competent conformity assessment bodies. International procedures and standards can assist in this respect.

To this end, it is important to have clear criteria for appointing competent conformity assessment bodies, especially where Japanese product standards differ from international ones. The rules, standards and procedures that determine the operation of conformity assessment bodies in the context of Japanese laws should be transparent, non-discriminatory and aligned with international standards, especially with the criteria enshrined in ISO/IEC guidelines. This would ensure that all competent third parties that have demonstrated their technical competence in accordance with and against international standards and practices could be recognised under the relevant Japanese laws.

The European Union welcomes the different schemes that have come into existence over the past years under various laws (such as the recently amended Electrical Appliances Safety Law and Building Standards Law) that allow competent foreign testing, inspection and certification bodies to perform conformity assessment functions under these laws. This move towards internationalisation is an important step towards meeting the overall objective of the Japanese government and the new Regulatory Reform Programme of harmonisation with international standards wherever possible. The "Progress Report on Reviewing the System of Standards Certification, etc." published in April 2001 in accordance with the Regulatory Reform Programme contains useful data. In particular, the EU welcomes the information provided by METI on the criteria for accrediting conformity assessment body by legislation making reference to the corresponding provisions for Guide 65 or ISO 17020. The entry into force of the EU-Japan Mutual Recognition Agreement (MRA) facilitates market access to Japan for EU exporters for the sectors covered by this agreement (electrical products, radio-telecommunication equipment, good laboratory practice and good manufacturing practice). Also, it certainly facilitates confidence building and exchange of information between regulators and operators in the conformity assessment field. A smooth and pragmatic implementation of the MRA is desirable.

Fuller deregulation leading to greater self-certification, however, would significantly further facilitate trade even in these sectors. More importantly, there are many sectors where an MRA is not possible or not envisaged for the time being, and which would greatly benefit from the above-mentioned proposals.

Priority reform proposals:

a. *The EU requests the Japanese authorities concerned to streamline their regulatory procedures, make greater reference to international standards and performance norms, and align their criteria for the recognition of conformity assessment bodies – including the non-discrimination of foreign testing and inspection bodies – with ISO/IEC standards and practices.*

b. *The EU would be grateful for comprehensive information on all legislation that permits the designation of foreign conformity assessment bodies. Such information should take a user-friendly form in order make clearly understandable additional requirements to ISO/IEC standards/guidelines by listing the correspondence that exists between, on the one hand, standards and criteria for recognition and designation, and, on the other hand, the comparable ISO/IEC standards and criteria. One means of ensuring that such important information is publicised would be for the Japanese government to create a single database which lists (i) the law or enforcement order which allows the relevant minister to accredit a foreign conformity assessment body, (ii) the criteria applicable to such accreditation, and (iii) the degree of compatibility of these criteria with ISO/IEC standards/guidelines.*

2.2.2. Building standards – formaldehyde emission regulations for construction products

New regulations on formaldehyde emission levels for constructions products for use in building interiors have been introduced by the Ministry of Land, Infrastructure and Transport MLIT), and entered into force on 1 July 2003. While the EU does not dispute the Japanese government's aim to improve the interior environment of new buildings for reasons of human health, the implementation of these regulations continues to cause concern for EU exporters. Owing to late and insufficient implementation of the regulations, notably the late availability of final details of the testing methods needed to obtain the necessary certification, many exporters' products are now *de facto* excluded from the Japanese market.

According to the type of product involved, testing and performance evaluation are required under JAS or JIS rules, or via the Ministerial Approval scheme of the Building Standards Law (BSL). The majority of the (mostly wooden, including cork) products exported by the EU are covered by either the Ministerial Approval or JAS schemes. However, no testing organisations in Europe have been approved to carry out testing or performance evaluation, and EU exports are thus subject to considerable costs and delays because of capacity bottlenecks amongst the Japanese performance evaluation bodies and testing institutes approved by MLIT. Volumes of trade which constitute up to 20% of the export profile of certain EU Member States to Japan have thus been put in jeopardy.

Following an exchange of correspondence between Commissioner Lamy and Japanese Foreign Minister Kawaguchi on the trade-related aspects of this problem (letter of 18 August and reply of 29 August), MLIT has come forward with a scheme which will allow Japanese performance evaluation bodies effectively to sub-contract testing to approved testing institutes in the EU. Once implemented, this should

improve access by EU companies to obtaining Japanese certification and reduce the costs in time and money of shipping samples for testing and approval. The EU welcomes this initiative as a positive step towards helping EU exporters to comply more easily with the new requirements under the BSL. Much will depend on the speed with which MLIT determines that candidate institutes in Europe comply, *mutatis mutandis*, with the requirements of the BSL, and on commercial contractual negotiations between such testing institutes and Japanese performance evaluation bodies.

In the long term, however, the EU seeks further improvements in the speed and ease with which EU products can obtain Japanese certification.

Priority reform proposals:

a. Notwithstanding the EU's request for an interim moratorium for EU products concerned by this measure until 1 January 2004:

(i) continue to make all efforts to accelerate the process of Ministerial Approval for products which have initiated the approval process but which have not yet been approved;

(ii) ensure that, as a rule, the Ministerial Approval process for new products is completed within a maximum of six weeks. Approvals should be product-specific only and not also company-specific;

(iii) make all efforts to promote and facilitate subcontracting by Japanese performance evaluation bodies of the testing function under the Ministerial Approval scheme to EU testing institutes;

(iv) in the medium term, examine with the European Commission on what basis the relevant CE mark (based on standards EN717-1 and 717-2) could be used in order to fulfil the technical appraisal requirements under the Ministerial Approval scheme.

b. Simplify and accelerate the application process for JAS production process approval, which will enable manufacturers in Europe to affix the JAS mark themselves.

c. Simplify and accelerate the process of obtaining Registered Foreign Certification (RFCO) status under JAS and JIS rules.

d. Explore with the European Commission the automatic acceptance of CE-marked construction products for installation according to their intended use as long as their declared characteristics fulfil the requirements of Japanese regulations

2.2.3. Motor vehicles

Adoption of UN-ECE Regulations

The European Union believes that the international harmonisation of automobile regulations is in the fundamental interest of all producing nations, especially as the auto industry in every aspect is a truly global industry. The European Union appreciates greatly Japan's full participation under the revised 1958 UN-ECE Agreement, but request that the Japanese side will sign up quickly to a significant number of the annexed regulations. The Japanese government has announced an adoption rate of about 30 regulations, out of over 100 regulations, by the end of FY 2003 -or about 5 to 6 regulations per year. The European Union is of the firm opinion that this adoption rate should be speeded up. The EU also believes that Japan should concentrate on the adoption of regulations in areas where the absence of harmonisation with the international standards is the most disruptive to trade, thereby saying that concerns expressed by importers must be appropriately considered. Early adoption of the maximum number of UN-ECE regulations will help to build on and consolidate the improvements which have already been made in reducing the time needed for type approval of motor vehicles in Japan.

Priority reform proposal:

The EU has a long standing request for Japan to speed up its adoption of UN-ECE regulations. EU notes that Japan aims for the adoption of 30 UN-ECE regulations by 2003. The EU requests that (i) beyond 2003 the number of regulations adopted per year could be accelerated considerably, and (ii) Japan should in this work incorporate the following priority list of UN-ECE requirement: Japan should accede to all remaining lighting regulations; viz UN-ECE R4/R20/R37/R48/R87/R98/ R99/R112 and R113. As a logical consequence of making safety a priority, the EU also hopes that Japan will give priority to the following package: UN-ECE R14 and R16. Other important regulations for adoption would be UN-ECE R43, R44, R46, R59, R90, R97 and R103.

2.3. Food safety and agricultural products

2.3.1. Food additives and flavourings

Recent scandals involving the use of food additives, including flavourings, have revealed major problems in the way food additives are approved for use in Japan. Many substances in common use around the world and recognized as being safe by international food safety bodies such as the Joint FAO/WHO Expert Committee on Food Additives (JECFA) are not allowed in Japan. Conversely, numerous substances have been approved in Japan that have not been reviewed and approved by the international scientific community.

While food safety must remain a priority, the manner in which Japan's MHLW has responded to recent scandals is a matter of serious concern to the European Union. A large number of food recalls ordered recently by MHLW have, as indeed publicly stated by the ministry, been made despite there being no human health concerns at stake. These recalls have involved products containing flavourings and additives manufactured in Japan (in some cases for over 30 years), as well as products in common use around the world – many of them imported from the European Union's 15 Member States. The EU deeply regrets the negative effects on Japanese consumers, many of whom have wrongly been led to believe that food they have found on the shelves for the past 30 years is potentially unsafe, European Union food producers and their Japanese partners are intent on respecting Japanese law and providing safe food products to Japanese consumers.

The European Union follows closely the work of the CODEX Alimentarius on determination of the safety of ingredients and additives, according to internationally accepted scientific methods. Further, the EU urges Japan to move towards international standards and bring its list of additives in line with the work of CODEX Alimentarius, an organization to which Japan adheres and provides support. In particular, research to determine a "positive list" of acceptable substances and residue levels has already been done by the international community and has been accepted, after serious consideration, by CODEX Alimentarius. Japan should act on this issue without delay to avoid the unnecessary problems now being experienced, and to help ensure a high level of consumer protection.

Priority reform proposal:

The EU urges the Japanese government to modernize Japan's list of accepted food additives in line with the applicable international standards – the CODEX Alimentarius – and to accept flavourings recognized as being safe by food safety evaluation bodies such as the Joint FAO/WHO Expert Committee on Food Additives (JECFA), the EC Scientific Committee on Food or the European Food Safety Authority.

In order for Japan to catch up as quickly as possible with international standards and practices, the EU urges the Government of Japan to approve as a priority those 38 additives/flavourings which appear on MHLW 's list of substances to be considered for quick approval (published on 9 January 2003). These substances should be approved as one package in place of the current one by one or group by group examination process which has proved inefficient.

2.3.2. Import of cut flowers, pot plants in approved growing media, fruit, vegetables - Japanese list of non-quarantine organisms

Japan's Plant Quarantine Law was partially revised and passed by the Diet in June 1996, but so far this revised law has had a limited effect on imports of plant products because in practice it does not make a scientifically justifiable, practical distinction between harmful ("quarantine") and non-harmful ("non-quarantine") organisms.

Japan's list of non-quarantine organisms is incomplete and many common organisms which are present both in Europe and Japan, such as aphids and mites, are not included on this list. Any plant products which have such non-harmful organisms on them are treated by Japan in the same way as if they were infested by harmful organisms and must be fumigated or rejected for import. The regulations are not in line with international standards and norms. In line with the Government of Japan's commitment set out in the deregulation package of 31 March 1998, regulations should be modified to conform to the principles of the WTO SPS Agreement.

In February 1999 the European Commission requested the addition of 9 priority organisms to the Japanese list of non-quarantine organisms, and this was repeated in a letter dated 28 July from then Director-General Legras to then Vice-Minister Kumazawa. In his reply of 24 January 2000, Mr Kumazawa refused to add the 9 organisms to the non-quarantine list, but indicated that Japan is studying the possibility of introducing tolerance levels and alternative methods of disinfection. The results of this study, which were promised in early 2001, are not yet available to the European Commission. Much as the Commission appreciates the efforts made by the Japanese phytosanitary experts to produce a proposal for tolerance levels for these organisms with regard to cut flowers for the other items, such as fruit and vegetables, no further progress has been made, and no indications on tolerance levels have been presented by the Japanese side. Moreover, in its reply of May 2003 to the EU proposals of last year, the Government of Japan has failed again to provide any clear explanation on why it could not accept the EU's request.

Priority reform proposal:

The EU requests that the Japanese list of non-quarantine organisms be extended to include all non-harmful organisms found in, fruit and vegetables, cut flowers, pot plants in approved growing media. As a first step the 9 organisms specifically requested by the EU should be added to the list. In parallel, tolerance levels should be established for quality viruses which are not on the non-quarantine list. These tolerance levels should benefit all EU Member States.

2.3.3. "Regionalisation" – recognition of the EU's single market as regards animal and plant products

Japan has not yet recognised that a single market for animal and plant products exists in the EU and has not yet implemented the provisions of the Sanitary and Phytosanitary Standards (SPS) agreement of the World Trade Organisation (WTO) on regionalisation with respect to this single market. Each EU Member State must therefore negotiate bilaterally and pass through lengthy approval procedures for each new variety or type of animal or plant product which it wishes to export to Japan.

The EU applies the principle of regionalisation internally within its external borders in accordance with international guidelines as explained in G/SPS/GEN/101. Japan can therefore have confidence in the legal Decisions taken at a European level with respect to regionalisation and consider the disease/pest free areas recognised by these Decisions when applying import measures on products from the EU.

As a result of ongoing discussions on this point, in 2000/2001 Japan accepted a proposal from the EU to conduct an informal case study using Classical Swine Fewer as an example to examine the feasibility of applying regionalisation in the way requested by the EU. The submission was made by the EU but still no comments have been received from Japan. A proposal to conduct a similar case study with plant products was not taken up by Japan so far.

Priority reform proposal:

The EU requests that Japan have confidence in the legal Decisions taken at a European level with respect to regionalisation and consider the disease/pest free areas recognised by these Decisions when applying import measures on products from the EU. EU measures on regionalisation are in full conformity with international standards of OIE, CODEX and EPPO. The need for the Member States to make 15 (soon 25) separate applications must be eliminated.

2.3.4. Regulatory procedures for acceptance of varieties of fresh fruit and vegetables

Although import authorisation has been granted by Japan for Spanish navel oranges and French golden apples,. the duration of SPS approval in Japan is far too long – it has taken up to 20 years for the approval of some citrus fruits. While the Japanese government has replied with respect to Spanish Salustiana and Clementina oranges that a public hearing will be held, the EU notes with regret that, owing to postponement by MAFF, no such hearing has yet taken place. Similarly, public hearings for Italian fruits and vegetables have not yet taken place.

Priority reform proposal:

The EU requests Japan to process import requests without undue delay especially with respect to several outstanding current applications (i.e. Spanish Clementina and Salustiana oranges, French apples, Italian fruits and vegetables (notably the orange variety Tarocco*), Belgian tomatoes, etc. SPS approvals should in future be processed quickly and without delay.*